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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/014,128 | 12/07/2001 | John Carrino | INVIT1290-2 | 1163 |

7590 02/04/2004

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| EXAMINER | |
|---|---|
| SIEW, JEFFREY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/014,128 | CARRINO ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey Siew | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *57-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/7/01* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I is acknowledged. The traversal is on the ground(s) that Group III contain components useful for practicing the methods of claims of Group I and would not pose undue burden. This is not found persuasive because according to MPEP 806.5(h) provides a proper basis of restriction a product and method when the product claimed may be used for a materially different process. Group III components may be used in hybridization and detection assays.

The requirement is still deemed proper and is therefore made FINAL.

Claims 57-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

### *Specification*

**2.** The drawings contain nucleotide sequences which must be identified by SEQ ID NO.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall bc cntitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,8-10,12-14,25,26,28-31,37-41, 44,45, 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Shuman (US5,766,891 June 16, 1998).

Shuman teach a method of generating a double stranded recombinant nucleic acid comprising contacting a first ds nucleotide derived from subpopulation and a second ds nucleotide sequence and at least one topisomaterase such that topoisomerase covalently link both strands of first sequence to second sequence generating a ds recombinant molecule (see whole doc. esp. abstract & col. 6 line 21). In particular they teach PcR amplifying a donor duplex DNA molecule with oligonucleotide primers containing sequence specific topoisomerase cleavage site, incubating the donor duplex DNA with a sequence specific topoisomerase, resulting in the formation of a sequence specific topoisoemrase donor duplex DNA incubating with plasmid vector with 5 overhand compatible with donor and incubating and transforming vector into host cell (see col. 6 line 60- col. 7 line 6). They teach that the transforming host cell with DNA sequence to encoding a polypeptide activity (see abstract). They teach using vaccinia DNA topoisomerase which is type 1 topoisomerase (see col. 1 line 25-26). They teach regulatory elements including promoter and enhancer to bind RNA polymerase. They lac promoter, start codon and termination codon (see col. 7 line 27-40). They also teach poly histidine tags tags (see col. 5 line 34). They teach using affinity labels such as biotin introduced into the DAN product to purify the product (see col. 6 line 21-26).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-34,36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuman (US5,766,891 June 16, 1998).

The teachings of Shuman et al are described previously.

Shuman et al do not teach using a third ds sequence.

One of ordinary skill in the art would have been motivated to further bind a third sequence in order to build a desired construct. It was well known in the art to build long constructs from smaller fragments. It would have been prima facie obvious to further construct

longer ds sequences by covalently bonding with Shuman et al's topoisomerase to build longer sequences for insertion into vectors.

5. Claims 6,7,11,15-24,27,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuman (US5,766,891 June 16, 1998) in view of Yarovinsky (US2002/0068290 June 6, 2002).

The teachings of Shuman et al are described previously.

Shuman et al do not teach pox virus vaccinia, topoisomerase charged adapters.

Yarovinksy et al teach topoisomerase activated oligonucleotide adapters for covalently bonding sequences (see whole doc. esp. abstract & paragraph 0010). They teach pos virus (paragraph 0062). They teach joining various targets particularly using Shuman et al's technique (see paragraph 004).

One of ordinary skill in the art would have been motivated to apply Yarovinksy et al's topoisomerase activated oligonucleotides to Shuman et al's method of covalent linkage in order to bind the amplified sequences into vectors. Yarovinsky et al state that topoisomaerase activated oligonucleotides provide for rapid joining of target to adaptor sequences (see paragraph 005). It would have been prima facie obvious to apply Yarovinksy et al's adaptors to Shuman et al's method in order to quickly join amplified sequences into vectors.

6. Claims 42 & 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuman (US5,766,891 June 16, 1998) in view of Seed et al (US5,830,731 Nov. 3, 1998).

The teachings of Shuman et al are described previously.

Shuman et al do not teach expression of T7 suppressor.

Seed et al teach T7 suppressor gene in expression vector (see col. 6 line 24).

One of ordinary skill in the art would have been motivated to apply Shuman et al's method of construction to expression Seed et al's T7 suppressor gene in order to express and produce T7 suppressor. Seed eta l state that the T7 suprressor may be used in diagnostic and therapeutic purposes(see abstract). It would have been prima facie obvious to use Shuman et al's cloning procedure in order to quickly express and produce Seed et al's T7 suppressor gene.

7. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuman (US5,766,891 June 16, 1998) in view of Trono et al (US5,605,802 Feb. 25, 1997).

The teachings of Shuman et al are described previously.

Shuman et al do not teach histidine tag attached to DNA sequences.

Trono et al teach histidine tags in expression vectors (see col.1 2 line 17).

One of ordinary skill in the art would have been motived to apply Trono et al's teaching of histidine tags to Shuman et al expression system in order to purify the expressed protein. It was well known and commonly practiced in the art to fuse histidine tags to genes in vectors to aid in affinity purification. It would have been prima facie obvious to apply Trono et al's histidine tags to the expressed proteins in Shuman et al's system in order to quickly purify the protein to isolation.

SUMMARY

8. No claims allowed.

**CONCLUSION**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

JEFFREY SIEW
PRIMARY EXAMINER

February 2, 2004